

Food and Drug Administration, HHS

§ 175.320

Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 175.320 Resinous and polymeric coatings for polyolefin films.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from one or more of the basic olefin polymers complying

with §177.1520 of this chapter. The base polyolefin film may contain optional adjuvant substances permitted for use in polyolefin film by applicable regulations in parts 170 through 189 of this chapter.

(b) The coatings are formulated from optional substances which are:

(1) Substances generally recognized as safe for use in or on food.

(2) Substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, by prior sanctions, or approvals.

(3) Substances identified in this paragraph (b)(3) and subject to such limitations as are provided:

List of substances	Limitations
<p>(i) Resins and polymers:</p> <p>Acrylic acid polymer and its ethyl or methyl esters.</p> <p>Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, and the copolymer subsequently reacted with formaldehyde and butanol.</p> <p>Butadiene-acrylonitrile copolymer.</p> <p>Butadiene-acrylonitrile-styrene terpolymer.</p> <p>Butyl rubber.</p> <p><i>N,N</i>-Diphenyl-<i>p</i>-phenylenediamine</p> <p>2-Ethylhexyl acrylate copolymerized with one or more of the following:</p> <p>Acrylonitrile.</p> <p>Itaconic acid.</p> <p>Methacrylonitrile.</p> <p>Methyl acrylate.</p> <p>Methyl methacrylate.</p> <p>4,4'-Isopropylidenediphenolepichlorohydrin average molecular weight 900.</p> <p>Melamine-formaldehyde as the basic polymer or chemically modified with methyl alcohol.</p> <p>Methacrylic acid and its ethyl or methyl esters copolymerized with one or more of the following:</p> <p>Acrylic acid.</p> <p>Ethyl acrylate.</p> <p>Methyl acrylate.</p> <p>α-Methyl styrene polymer.</p> <p>α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).</p> <p>Petroleum alicyclic hydrocarbon resins</p> <p>Polyamide resins (CAS Reg. No. 68139-70-8), as the basic resin, derived from:</p> <p>Dimerized vegetable oil or tall oil acids containing not more than 20 percent of monomer acids.</p> <p>Azelaic acid (CAS Reg. No. 123-99-9) in an amount not to exceed 3.7 percent by weight of the polyamide resin.</p> <p>Ethylenediamine (CAS Reg. No. 107-15-3).</p> <p>Piperazine (CAS Reg. No. 110-85-0) in an amount not to exceed 6.4 percent by weight of the polyamide resin.</p>	<p>For use only as a polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.</p> <p>For use only in coatings that contact food under conditions of use D, E, F, or G described in table 2 of § 176.170(c) of this chapter, provided that the concentration of α-methylstyrene-vinyltoluene copolymer resins in the finished food-contact coating does not exceed 1.0 milligram per square inch of food-contact surface.</p> <p>As defined in § 176.170 of this chapter. Blended with butyl rubber for use as a component of coatings on polyolefin fabric for bulk packaging of raw fruits and vegetables and used at a level not to exceed 30 percent by weight of the total coating solids.</p> <p>For use only in coatings for polypropylene films that contact food at temperatures not to exceed room temperature.</p>

List of substances	Limitations
<p>Polyamide resins, derived from dimerized vegetable oil acids (containing not more than 20% of monomer acids) and ethylenediamine, as the basic resin.</p> <p>Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acids (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin.</p> <p>Polyester resins formed by reaction of one or more of the following polybasic acids and monobasic acids with one or more of the following polyhydric alcohols:</p> <p>Polybasic acids:</p> <p>Adipic.</p> <p>Azelaic</p> <p>Dimerized fatty acids derived from:</p> <p>Animal, marine or vegetable fats and oils.</p> <p>Tall oil.</p> <p>Fumaric.</p> <p>Isophthalic.</p> <p>Maleic.</p> <p>o-Phthalic.</p> <p>Sebacic.</p> <p>Terephthalic.</p> <p>Trimellitic.</p> <p>Monobasic acids:</p> <p>Fatty acids derived from:</p> <p>Animal, marine, or vegetable fats and oils.</p> <p>Gum rosin</p> <p>Polyhydric alcohols:</p> <p>1,3-Butylene glycol.</p> <p>Diethylene glycol.</p> <p>2,2-Dimethyl-1,3-propanediol.</p> <p>Dipropylene glycol.</p> <p>Ethylene glycol.</p> <p>Glycerol.</p> <p>Mannitol.</p> <p>α-Methyl glucoside.</p> <p>Pentaerythritol.</p> <p>Propylene glycol.</p> <p>Sorbitol.</p> <p>Trimethylol ethane.</p> <p>Trimethylol propane.</p> <p>Polyethylenimine</p> <p>Polystyrene.</p> <p>Polyvinyl acetate.</p> <p>Polyvinyl chloride</p> <p>Siloxanes and silicones: platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083–18–1 and CAS Reg. No. 68083–19–2) with methylhydrogen polysiloxane (CAS Reg. No. 63148–57–2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037–59–2). The following substances may be used as optional polymerization inhibitors:</p> <p>3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107–54–0), at a level not to exceed 0.53 weight percent;</p> <p>1-Ethynylcyclohexene (CAS Reg. No. 931–49–7), at a level not to exceed 0.64 weight percent;</p> <p>Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054–10–4), at a level not to exceed 1.0 weight percent;</p> <p>Methylvinyl cyclosiloxane (CAS Reg. No. 68082–23–5); and</p>	<p>For use only in coatings for polyolefin films that contact food at temperatures not to exceed room temperature.</p> <p>For use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.</p> <p>For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170(c) of this chapter, table 1, under Category VIII, and under conditions of use E, F, or G, described in table 2 of § 176.170(c) of this chapter.</p> <p>As defined in § 178.3870 of this chapter. For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170(c) of this chapter, table 1, under Category VIII, and under conditions of use E, F, or G described in table 2 of § 176.170(c) of this chapter.</p> <p>For use only as a primer subcoat to anchor epoxy surface coatings to the base sheet.</p> <p>Platinum content not to exceed 150 parts per million.</p>

List of substances	Limitations
<p>Tetramethyltetravinylcyclotetrasiloxane (CAS Reg. No. 2554-06-5).</p> <p>Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1), with methyl hydrogen polysiloxane (CAS Reg. No. 63148-57-2). Dimethyl maleate (CAS Reg. No. 624-48-6) and vinyl acetate (CAS Reg. No. 108-05-4) may be used as optional polymerization inhibitors.</p> <p>Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1), with methyl hydrogen polysiloxane (CAS Reg. No. 63148-57-2). Dimethyl maleate (CAS Reg. No. 624-48-6), vinyl acetate (CAS Reg. No. 108-05-4), dibutyl maleate (CAS Reg. No. 105-76-0) and diallyl maleate (CAS Reg. No. 999-21-3) may be used as optional polymerization inhibitors. The polymer may also contain C₁₆-C₁₈ olefins (CAS Reg. No. 68855-60-7) as a control release agent.</p> <p>Styrene copolymerized with one or more of the following: Acrylonitrile. α-Methyl styrene.</p> <p>Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight (M_n) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent.</p> <p>Styrene-isobutylene copolymer.</p> <p>Terpene resins consisting of polymers of α-pinene, β-pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.</p> <p>2-Sulfoethyl methacrylate, sodium salt Chemical Abstracts Service No. 1804-87-1].</p> <p>Vinyl chloride-acetate, hydroxyl-modified copolymer or maleic acid-modified copolymer.</p> <p>Vinyl chloride copolymerized with one or more of the following: Acrylonitrile. Vinyl acetate. Vinylidene chloride.</p> <p>Vinylidene chloride copolymerized with one or more of the following: Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters. Acrylonitrile. Itaconic acid. Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters. Methacrylonitrile. Vinyl chloride.</p> <p>(ii) Plasticizers: Acetyl tributyl citrate. Acetyl triethyl citrate. Butyl phthalyl butyl glycolate. Butyl stearate. Dibutyl sebacate. Diethyl phthalate. 2-Ethylhexyl diphenyl phosphate.</p>	<p>Platinum content not to exceed 100 parts per million. For use only as a surface coating under the following conditions:</p> <ol style="list-style-type: none"> 1. In coatings for olefin polymers provided the coating contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under Types I, II, VI, and VII-B when used under conditions of use E, F, and G described in table 2 in § 176.170(c) of this chapter. 2. In coatings for olefin polymers provided the coating contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under Types III, IV, V, VII-A, VIII, and IX when used under conditions of use A through H described in table 2 in § 176.170(c) of this chapter. <p>Platinum content not to exceed 100 parts per million. For use only as a release coating for pressure sensitive adhesives.</p> <p>For use only in contact with foods of Types IV-A, V, and VII in table 1 of § 176.170(c) of this chapter, under use conditions E through G in table 2 of § 176.170(c), and with foods of Types VIII and IX without use temperature restriction.</p> <p>For use only in copolymer coatings under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.</p>

List of substances	Limitations
<p>Ethyl phthalyl ethyl glycolate. Glycerol monooleate Glycerol triacetate. Triethyl citrate.</p> <p>(iii) Adjuvants (release agents, waxes, and dispersants): Acetone. Amides (unsubstituted) of fatty acids from vegetable or animal oils. <i>n</i>-Butyl acetate. <i>n</i>-Butyl alcohol. Candelilla wax. Carnauba wax.</p> <p>5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172–55–4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682–20–4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935–90–2) and optionally containing magnesium nitrate (CAS Reg. No. 10377–60–3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight)..</p> <p>1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691–65–7).</p> <p>Ethyl acetate. Fatty acids from vegetable or animal oils and their aluminum, ammonium, calcium, magnesium, and sodium salts. Hexane. Methyl ethyl ketone. <i>N,N</i>-Dioleylethylenediamine (CAS Reg. No. 110–31–6) ...</p> <p>Petroleum waxes conforming to specifications included in a regulation in subchapter B of this chapter. Polyvinyl alcohol, minimum viscosity of 4% aqueous solution at 20 °C of 4 centipoises and percent alcoholysis of 87–100.</p> <p>Sodium dioctyl sulfosuccinate. Sodium dodecylbenzenesulfonate. Sodium lauryl sulfate. Sorbitan and sorbitol esters of fatty acids from vegetable or animal oils. Spermaceti wax. Tetrahydrofuran. Toluene.</p> <p>(iv) Preservatives: Silver chloride-coated titanium dioxide</p>	<p>For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulation.</p> <p>For use as an antimicrobial agent at levels not to exceed 500 milligrams per kilogram in emulsion-based silicone coating.</p> <p>For use only in ionomeric resins complying with § 177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with § 177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article.</p> <p>For use only as a dispersing agent at levels not to exceed 6% of total coating weight in coatings for polyolefin films provided the finished polyolefin films contact food only of the types identified in § 176.170(c) of this chapter, table 1, under Types V, VIII, and IX.</p> <p>For use only as a preservative in latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.</p>

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.17(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface.

(d) Acrylonitrile copolymers identified in this section shall comply with

the provisions of § 180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 43 FR 7206, Feb. 21, 1978; 45 FR 6541, Jan. 29, 1980; 47 FR 22512, May 25, 1982; 49 FR 36497, Sept. 18, 1984; 50 FR 47209, Nov. 15, 1985; 56 FR 49674, Oct. 1, 1991; 61 FR 14246, Apr. 1, 1996; 63 FR 71017, Dec. 23, 1998; 64 FR 2568, Jan. 15, 1999; 65 FR 6892, Feb. 11, 2000; 65 FR 37041, June 13, 2000]